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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,852	08/31/2001	Kevin P. Baker	P2548P1C13	8469

7590 11/25/2003

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/944,852

Applicant(s)

BAKER ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): Claim 27 under 35 USC 112(2) regarding indefinite language.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 22-27.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Claim 26 stand objected to because instant claim recites the article 'a' before the word "labeled." for the same reasons of record as set forth in the office action mailed on 08/12/03. Appropriate correction is required.

Claim 22-27 would stand rejected under 35 USC 112(1) regarding enablement issues for the same reasons of record as set forth in the office action mailed on 08/12/03.

Applicant argues that MLR is a well-established in-vitro assay for assessing the ability of a test compound to stimulate or suppress T cell proliferation, and consequently the immune response of an individual. Applicant argues that the specification discusses the inhibitory activity of PRO361 (with regard to T cell proliferation), as demonstrated in a MLR assay. Applicant further argues that methods for preparing antibodies have been routine in the art, which is predictable. Applicant argues that one of skill in the art would know that antibodies to PRO361, wherein PRO361 is acting as an agonist, are useful for suppression of an immune response. Alternatively, an antibody to PRO361, wherein PRO361 is acting as an antagonist or inhibitor, would find utility in stimulating a T cell response. Applicants maintain that the application is enabled and that undue experimentation is not required to practice the claimed invention.

However, this is found NOT persuasive because the function of PRO361 appears to be unknown. At best the specification only teaches PRO361 is either a mucin or chitinase that may be associated with cancer, plant pathogenesis or receptor functions (spec. page 59). Since the function of PRO361 is unknown one skill in the art would have to engage in an inordinate amount of work and experimentation to find out not only the identity of what the antibodies of PRO361 are useful for but also the use of PRO361 itself. Even though the PRO361 inhibits the T cell proliferation in a MLR assay the specification fails to disclose under what circumstances an antibody to PRO361, would find utility in stimulating a T cell response. Under the law, the disclosure "shall inform how to use, not how to find out how to use for themselves." See *In re Gardner* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). For these reasons and those discussed in the previous Office action, the present claims fail to meet the enablement requirement under 35 USC 112(1)..